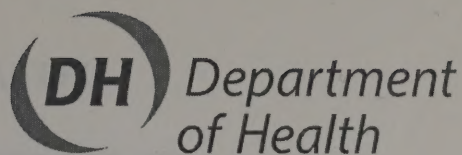


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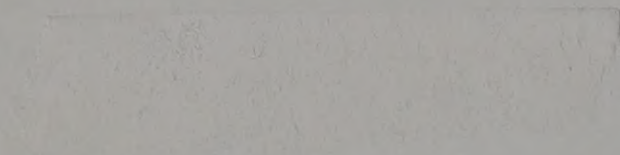
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Science and Innovation Strategy

September 2001

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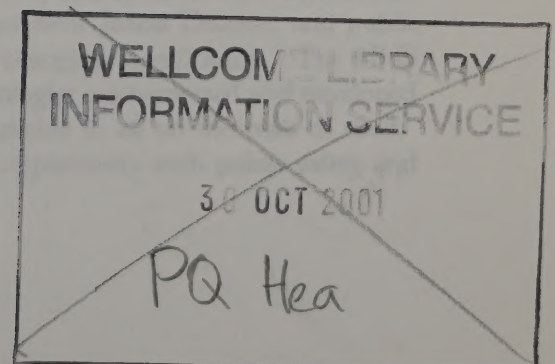
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DEPARTMENT OF HEALTH SCIENCE & INNOVATION STRATEGY

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September 2001



Chapter 1

Summary of Science and Innovation Strategy

Department of Health responsibilities

Role in science and innovation

Science and innovation goals

Major science and innovation priorities

The Department of Health's responsibilities

1.1 The Department of Health has responsibility for promoting and protecting public health, for the provision of health services and setting the policy for the delivery of social care, and is responsible for the stewardship of £48 billion of public funds (in England in 2001 - 2002). It is currently engaged in a major programme to transform the health and social care system to produce fairer, faster services that deliver better health and quality of life and tackle inequalities. This is reflected in the Department's Public Service Agreement targets. The programme to deliver these changes is set out in the NHS Plan, Our Healthier Nation and Social Care White Papers. As well as driving policy and service priorities, this programme also determines the Department's research priorities.

The Department's role in science and innovation

1.2 Science and innovation are essential for modern health and social care services and for the effective promotion of health and well-being. Advances in science and technology have revolutionised modern medicine providing the antibiotics, vaccines and other interventions that have helped improve the nation's health. The Department's responsibilities inevitably mean that its role in relation to science is very wide. It includes:

- encouraging innovation;
- sponsoring the healthcare industries;
- contributing through the NHS to the infrastructure for medical research;
- investing in new research;
- helping to translate research into practice and practical application;
- using scientific evidence to inform policy-making and service delivery;
- ensuring appropriate governance and ethical standards in health research; and
- regulating to protect patients.

Science and innovation goals

1.3 Science and technology are developing at an increasingly rapid rate. New opportunities arising from the human genome project and advances in biotechnology together with greater public expectations are increasing the opportunity and need for new investment. At the same time there are new threats to health, e.g. Creutzfeldt Jakob Disease, and public attitudes to and confidence in science and medicine are changing significantly. The NHS Plan commits the Government to ensuring that new technologies are harnessed and developed in the interests of society as a whole and that they are available to all on the basis of need. The challenge for the Department is to balance scientific opportunity with public safety and

acceptability, and this is reflected in the Department's high level science and innovation goals. These are:

- **to ensure that science and innovation lead to improved interventions for health and social care;**
- **to ensure that we work with our partners to sustain and develop the science base in health and social care;**
- **to ensure that policy and practice in health and social care are based wherever possible on sound science and research;**

and at the same time

to ensure that the rights, health, and safety of the public and patients are protected and their interests reflected.

1.4 The strategies to achieve these goals are described in this paper. The paper does not attempt to capture all the innovative developments being taken forward in modernising the NHS and social care; rather it focuses on those which are science and technology based.

Major science and innovation priorities

1.5 This paper identifies Departmental priorities for science and innovation over the next five to ten years, the main ones of which are, for the first goal

- to develop a major research and development programme in **genetics** and health;
- to implement measures to improve the competitiveness of the **pharmaceutical and other healthcare industries;**
- to develop and implement a new strategy for **technology development and transfer;**
- to develop a more strategic approach to promoting **innovation in the NHS;**
- to harness **new information and communication technologies** to improve services;

for the second goal

- to strengthen partnerships between NHS, industry, the universities, Research Councils and other funders to promote **synergy in the science base;**
- to improve the **research infrastructure** in the NHS;

- to introduce new arrangements for **supporting science in the NHS**;
- to deliver a **research workforce capacity strategy** for health and social care research;

for the third goal

- to promote a more strategic approach to research investment by the Department, the NHS and their partners and **deliver the evidence base for the NHS Plan priorities**, including children, older people, cancer, coronary heart disease, mental health and health inequalities;
- to ensure that the use of **scientific advice in policy making** follows best practice and guidance from the Government's Chief Scientific Adviser;
- to provide the systems for better **knowledge management** in health and social care, in particular the National electronic Library for Health;

for the fourth goal

- to develop approaches to **risk assessment** in collaboration with other Government departments;
- to introduce and implement a **Research Governance Framework** for health and social care;
- to improve the framework for handling **confidential patient information**; and
- to increase the **involvement of consumers** in the research and scientific advisory systems.

1.6 Details of these priorities are set out in the relevant chapters on the strategic science and innovation goals.

Chapter 2

Innovation and technology transfer

Goal: To ensure that science and innovation lead to improved interventions for health and social care

Genetics

Supporting and working with industry

Support for technology development and transfer

Encouraging innovation in the NHS

Information and communication technologies

2.1 To be successful in delivering effective health and social care and improvements in health and quality of life, we need to be successful in generating and disseminating knowledge and exploiting it for the benefit of patients, users and the public. In particular we need to support and facilitate innovation to turn ideas and knowledge into new products, interventions and services. Industry, the universities, other research establishments and the NHS are all sources of new ideas and new technologies; partnership between these is critical to maximising benefits to patients and to realising wider commercial benefits for the nation.

Genetics

2.2 Now that we have the first provisional map of the human genome it is vital that the NHS plays an active and collaborative role in realising the benefits for human health from advances in genetics. The Department is drawing up a genetics and health strategy to ensure that health policy and services keep pace with the opportunities and developments that will arise while ensuring that there is a wider dialogue about their ethical, legal and social implications. A key element of the strategy is the promotion of research to increase our understanding of the basis of common adult diseases, to develop new interventions and to evaluate all aspects of emerging developments, from laboratory testing to counselling services. The strategy will bring together the NHS R&D science base, industry and charitable sectors alongside NHS staff and patients. [See Box A].

Supporting and working with industry

2.3 The Department of Health is the sponsor department for the pharmaceutical and other healthcare industries. This involves helping ensure that the industry has an environment in which it can flourish to benefit the nation's health and wealth. Working in partnership with industry is increasingly important in harnessing the benefits of new technologies for health and quality of life. The research-based **pharmaceutical industry** is the most important innovative high-tech industry in the UK, accounting for 23% of all expenditure on manufacturing R&D. The Department has a major role to play in ensuring that the UK remains an attractive base for industry. The Pharmaceutical Industry Competitiveness Task Force (PICTF) was set up in 2000 to develop a deeper partnership between industry, the NHS and Government and to ensure that the UK-based pharmaceutical industry keeps its competitive edge. [See Box B].

Box A - Genetics research

A strategy for research and development in genetics is being developed, the objectives of which are to:

- deliver an evidence base that will facilitate the identification of best practice and support the delivery of genetic services by the NHS;
- contribute to the exploitation of genomics research; and
- support the UK biopharmaceutical sector.

The strategy will:

- identify research opportunities in human genomics;
- develop and fund appropriate applied R&D programmes; and
- develop partnerships with other research funders including the Research Councils, charities and industry.

Delivery mechanisms are by directly commissioned research and through jointly funded initiatives. Opportunities include:

- the development of a preventive health service based on determining the genetic susceptibility of individuals to disease;
- the introduction of targeted therapy through the support of pharmacogenetics; and
- improved diagnosis and treatment of disease.

Threats include:

- insufficient research capacity in specific disciplines;
- complex ethics approval process, particularly over the creation of prospective cohorts for susceptibility studies; and
- confidentiality policies on access to genetic information.

As a first step, the Department will be:

- commissioning knowledge parks in genetics and health. A new £10 million fund - the Genetics Knowledge Challenge Fund - has been established to create up to four knowledge parks in England over the next few years. A joint partnership with the Department of Trade and Industry has been agreed and a joint commissioning programme is being developed. It is intended that the genetics knowledge parks will contribute to all aspects of emerging developments in genetics, from the development of test methods to evaluating the requirement for counselling patients;
- contributing with other Government departments and medical charities to a longer-term study of the interactions of genetics and the environment in common diseases of adults such as cancer and heart disease and diabetes and commissioning research to explore the most effective mechanisms for delivering genetic services in both hospital and primary care settings.

These powerful techniques for understanding and treating illness also raise other important issues. The Government has set up the Human Genetics Commission to advise on the social, ethical and legal implications of developments in genetics.

Box B - The Pharmaceutical Industry Competitiveness Task Force (PICTF)

PICTF was set up by the Prime Minister in March 2000 to look at the action needed to ensure that the UK remains an attractive place for the R&D pharmaceutical industry to locate its business in an increasingly competitive global environment. The Task Force brought together senior representatives from industry and Ministers from across Government to examine issues of concern to the UK-based pharmaceutical industry.

The Task Force looked at intellectual property rights, the relationship of the UK-based R&D Industry with its home market, the science base and biopharmaceuticals, the EU medicines licensing regime, clinical research in the UK and the overall competitiveness of the UK economic climate for R&D based industry. All parties agree that its report to the Prime Minister in March 2001 marks the start of a new partnership between industry and Government.

The PICTF report sets out action taken or in hand on a number of issues relevant to the Science and Innovation Strategy:

- industry and Government agreed on the essential role that intellectual property rights play, and should continue to play, in the flow of innovative medicines;
- it was agreed to streamline licensing procedures for essential research involving animals, cutting red tape and improving animal welfare. This complements amendments made to the Criminal Justice and Police Act and the Malicious Communications Act to tackle harassment and intimidation by animal rights campaigners;
- better use of NHS databases for pharmaceutical research and development was agreed;
- the industry and Government agreed positions on a range of medicines policy issues under discussion in the European Union, including issues around EU enlargement and key areas of IPR protection;
- measures were agreed to improve start-up times for clinical trials in the NHS, to improve cost transparency and to clarify responsibilities for research in the NHS sponsored by commercial interests and others;
- indicators of performance and competitiveness were agreed which will allow Government and industry to monitor the progress of the UK as a competitive location for R&D pharmaceutical investment.

2.4 Research is key to the future flow of new medicines and is the cornerstone of a successful pharmaceutical industry. Clinical trials are particularly crucial to the speed with which new medicines reach patients; we need to ensure that these can proceed without unnecessary delays while protecting the interests of patients. The **Medicines Control Agency** (MCA), an executive agency of the Department of Health, is responsible for regulating medicines for human use in the UK, including clinical trials of new medicines. The MCA has developed an interactive approach to industry in dealing with novel products, helping the pharmaceutical industry to develop safe and effective new drugs which has also been a factor in attracting biotechnology companies to conduct their trials in the UK. The MCA also played an active role in negotiating the recently adopted European directive on clinical trials. The directive will introduce streamlined procedures across the European Community that will provide an environment where new medicines can be developed safely and rapidly whilst ensuring a high level of protection for clinical trial subjects.

2.5 The MCA maintains an effective dialogue with the pharmaceutical industry on a range of regulatory issues. There is contact between MCA officials and industry representatives during drug development and post-authorisation; advice is given on the

interpretation of the legislation, related guidance and standards; consultation is undertaken on strategic matters, for example on negotiations on the Clinical Trials Directive; and there are periodic meetings with the trade associations for the sharing of information.

2.6 The MCA is a key player in the European medicines regulatory system and continues to participate actively on behalf of the EU in inspecting manufacturers and laboratories in third countries, and in developing mutual recognition agreements on inspection and Good Manufacturing Practice between the EU and Australia, Canada, New Zealand, Switzerland and the USA. Through its work on the global initiative to harmonise controls on medicines (via the International Conference on Harmonisation), the MCA has contributed to the development of international guidelines, most recently on Good Manufacturing Practice for active pharmaceutical ingredients. The MCA also provides an export certification service where companies wish to market medicines already available in the UK in a country outside the EU.

2.7 All these activities help the pharmaceutical industry to develop and market their products within the regulatory framework for medicines. The Clinical Research Working Group of PICTF considered how to create a more competitive clinical research base in the UK, and identified start up times, recruitment and research quality, and research costs as issues affecting competitiveness. It also set out an action plan to address these issues, including performance indicators to monitor progress. A particular outcome from the working group will be a joint Department of Health - Pharmaceutical Industry partnership agreement on future interactions and closer collaboration.

2.8 The **Biotechnology** industry is a major growth area and one in which the UK is leading research and development investment in Europe. It has already brought advances in diagnostic and medicinal products and has considerable potential to provide for further improvements in human health. The MCA has taken a leading role in Europe and in the International Conference on Harmonisation in developing regulatory controls for biological and biotechnological medicinal products, including those derived from emerging technologies. The Department of Trade and Industry leads on sponsorship for the wider biotechnology industry.

2.9 The **medical devices** sector of the UK healthcare industries makes a significant contribution to the economy with sales in the UK of several billion pounds and healthcare industries export sales of over £1billion. The industry has a number of large international players. Some, such as Smith and Nephew and Smiths Group, are based in the UK. There are also a significant number of small and medium sized enterprises. The number of players reflects the very wide range of medical devices. Though some devices use well-established technology, many, for example scanning equipment and implantable devices, are in a constant state of development. As well as other market opportunities, the modernisation of the NHS provides the industry with a stimulus for development.

2.10 Major advances in technology are coming together to lead innovation in the devices sector. These include developments in software (often harnessed to older technology such as that for artificial limbs), nano-technology, molecular biology and biomaterials. An innovative industry is undergoing a transition from its engineering/technological base into a life sciences industry. In-vitro diagnostic devices form a key area of growth, which will increasingly apply the results of genomic research.

2.11 The Department's **Medical Devices Agency** (MDA), which regulates clinical trials on new devices in the UK, helps support the development of the industry. It has already hastened the approval process by allowing research ethics committee consideration and regulatory authority assessment to be concurrent. This has resulted in a significant increase in the number of trials now being undertaken in the UK, which provides a stimulus to international companies to locate more of their R&D activity in the UK. The MDA and Department of Health are also in regular dialogue with the Association of British Healthcare Industries (ABHI) to identify other issues in the control of clinical trials and support for research and technology transfer which could be improved.

2.12 There is a global market for medical devices. The MDA has played a major role in a Global Harmonisation Task Force, which aims to reduce technical barriers to trade by harmonising device regulation across the world. The UK has also taken a leading role in putting into place Mutual Recognition Agreements between the EU and other key countries (USA, Australia and Canada), so that importing countries can accept regulatory conformity assessments made in exporting countries without the need for manufacturers to pay twice for assessments. The MDA will continue to play a leading role in global developments which will help the development of UK industry.

2.13 Within the UK, the MDA undertakes extensive dialogue with ABHI and with manufacturers during the development of new devices, provides test facilities for manufacturers developing wheelchairs and artificial limbs and it is running an increasing number of conferences with the industry as well as regular liaison meetings. The Department also advises the Engineering and Physical Sciences Research Council (EPSRC) on the running of the Integrated Healthcare Technologies (IntHeTech) sector within the Council's Innovative Manufacturing Initiative. IntHeTech aims to identify and resolve barriers to innovation in healthcare, and to identify new ways of working that have been successfully used in other manufacturing industries and could be applied within the healthcare industry to improve competitiveness.

Support for technology development and transfer

2.14 The dynamics of the healthcare industries sponsored by the Department are very different and affect the capacity for technology development and transfer. While the pharmaceutical industry is highly successful in developing new products, the Department has identified a number of other areas where some external support is needed to encourage technological development, and has provided support through a number of specific schemes, the main one of which is MedLINK. The scheme supports the development of new or improved medical devices for diagnostic, therapeutic or rehabilitation purposes; funding is on the basis of 50% public and 50% industrial partner. The Department is also a sponsor of TCS (formerly known as the Teaching Company Scheme) which supports partnerships between companies and the knowledge base, and provides advice to business support schemes, e.g. Smart funded by the Department of Trade and Industry. The Department of Health is participating in the Small Business Research Initiative.

2.15 More recently the Department has set up a scheme for technology development where there is no commercial sponsor. The NHS research and development programme on **New and Emerging Applications of Technology** (NEAT) funds the development of innovative health and social care products and interventions where there is no commercial sponsor for the technology in its present state of development. There has been extensive

interest in the programme and all projects recommended for funding by the Advisory Committee have been supported. Calls for proposals have been open and general to promote innovation but a close fit to NHS national priorities has still been attained.

2.16 One area in which the Department of Health plays a very particular role in technology development and transfer is in vaccines development. For example, in 1994 the Department identified the possibility that there would be an increase in Group C meningococcal disease, as had been seen elsewhere. Working with a consortium of agencies (Public Health Laboratory Service, National Institute for Biological Standards and Control, Centre for Applied Microbiology and Research, Institute for Child Health) and vaccine manufacturers, an accelerated vaccine development programme was supported. As a direct consequence of this research a full national immunisation campaign started in November 1999, and within a year all children and young people under 18 years had been offered the vaccine. There has already been a fall of more than 80% of cases, compared with the previous year and the UK is the first country in the world to use the new vaccine. To support longer term research on vaccines the Department, together with Biotechnology and Biological Sciences Research Council, Medical Research Council and Glaxo Smith Kline, provides support for the Edward Jenner Institute for Vaccine Research. The main focus of the Institute's programme is on fundamental immunology, formulation science and on developing models for vaccine assessment.

2.17 With the original £10million for the MedLINK scheme committed, the Department is undertaking a review of the scheme and future requirements. This will feed into development of a more systematic strategy for technology development and transfer which will clarify the Department's objectives for technology transfer, define the role of the Department of Health and others in delivering those objectives, aim to improve co-ordination between key players, and identify mechanisms for providing Department of Health support and facilitation, which is likely to include a flexible programme funding collaborative developments.

Encouraging innovation in the NHS

2.18 Improvement and maintenance of quality in an organisation such as the NHS requires a continuous cycle of the adoption of best practice, the development of innovative practice and the invention of new drugs, devices, procedures and equipment. Aspects of the latter are already supported through technology transfer schemes and through arrangements to capture, protect and develop intellectual property; the implementation of the NHS Plan, through the Modernisation Agency, will give added impetus to the adoption of best practice and the development of innovative practice.

2.19 In the NHS, innovation occurs primarily in the delivery of patient care, education and training of employees and research and development programmes. Innovation occurs naturally in the normal course of employment, and could be a novel treatment, a device, data, software, training material or a novel management system. Most of these innovations are best implemented through a non-commercial route, making them freely available through normal knowledge management processes when they have demonstrated a qualifiable health gain. However, some of these innovations need to be taken along a commercial route, and for these the management of the associated intellectual property is crucial. Implementation of the NHS Policy framework on the **exploitation of intellectual property** which began in 1998, is progressing and an analysis for 1999/2000 has shown that over 200 potential innovations had been identified so far and almost 100 patents had been filed. The

Department is putting in place systems to ensure that these innovations are identified and managed effectively so that they contribute not only to improved health care, but to enhanced UK economic prosperity and to income generation by NHS bodies. The measures in the Health and Social Care Act 2001, whereby the Secretary of State can now authorise NHS and Department of Health bodies to take a shareholding in spin out companies set up to exploit intellectual property (IP), give new possibilities for income generation. See Box C for details.

Box C - Exploitation of intellectual property

The Department's Framework for the Management of Intellectual Property (IP) within the NHS arising from research and development was introduced in 1998. At the same time, an IP Adviser for the NHS was appointed to advise on the implementation of the policy, the essential items of which are:

- commercial exploitation of IP is recognised as part of dissemination and uptake of knowledge;
- IP arising from research and development is to be owned by those best able to exploit that IP, which is normally the organisation carrying out the research;
- the NHS should seek benefit from commercial exploitation of IP whoever owns it, with IP addressed in every research contract;
- any NHS body owning IP has a responsibility to seek to exploit it; and
- any NHS body can retain income generated by commercial exploitation and share this with employees.

The Policy Framework covers IP arising from research and development, but much IP in the NHS arises from the direct provision and management of patient care. Current policy is being extended to include a Financial Framework for NHS bodies and employees operating within IP policy, which will be extended to include IP outside research and development; guidance on employment contracts for employees and on management arrangements for NHS bodies; and a Statement of Partnership between the NHS and its research partners.

The NHS IP Adviser is a member of the Treasury Group overseeing the implementation of the Science and Innovation White Paper, and works closely, through this group and outside, with the Patent Office to ensure that NHS policies remain consistent with national policy.

Exploitation of IP is a specialist task, and work is underway to establish viable structures to achieve an effective process. NHS bodies generally do not have the in-house IP management skills, and development of these complex skills within NHS bodies is inappropriate in the vast majority of cases. This is because the number of opportunities identified from the work of one NHS body would be insufficient to make such an activity viable.

The Department's advice is to encourage NHS bodies to work in a regional partnership with an external organisation, perhaps one it creates itself, which works under contract with each NHS body to exploit its IP. Lead Trusts are currently making bids, supported by other Trusts in the same Regional Development Agency area, to the capacity building element of the Public Sector Research Establishment Fund. The purpose is to secure support to establish these organisations. In addition to exploiting the IP, such an organisation also takes responsibility for identification of IP and raising IP awareness in each NHS body. Integration of this work with that carried out by organisations exploiting university IP, who generally have different strategic aims, is given high priority. Many of the IP outputs arise from joint work, and the management of the interface is being addressed.

Exploitation of IP has three main strategic aims for the NHS. In order of importance these are: to deliver improved healthcare for patients; to contribute to the economic prosperity of the country; and to produce a financial return to the NHS body.

An external organisation working under contract with NHS bodies will assess the value of IP against these benefits, and not just the financial return. Costs for the exploitation of IP are being met by the NHS and external sources. NHS bodies are encouraged to seek funding from external sources, and NHS research and development contracts from April 2001 include more specific guidance of what costs the NHS will meet.

The Health and Social Care Act 2001 allows the Secretary of State to approve proposals for NHS Trusts and employees to take equity in new companies set up to exploit IP. Guidance on these new arrangements is in preparation for publication alongside enactment.

The Department is ensuring that all its agencies, Non-Departmental Public Bodies and Special Health Authorities have processes in place to identify and exploit IP generated by their research programmes and by their normal business. A common policy, based on the Department's policy for the NHS, has been drafted and is to be introduced as soon as practicable. Exploitation processes will draw on, and be integrated with, the experience of NHS bodies.

2.20 Notwithstanding this initial programme, there is more that needs to be done to develop the NHS as an innovative organisation, one that sees innovation as integral to its business. Leadership to support innovation, and to provide the right climate and culture in which it can flourish, needs to be developed. There is a great wealth of innovative talent in the NHS but incentives, time and resources need to be provided to allow innovation to be pursued.

2.21 We are seeking external resources to support our activity (NHS Trusts have been particularly successful with the DTI Biotechnology Exploitation Platform scheme), and we are working collaboratively with Research Councils and other funders. Initial steps include:

- participating in existing schemes: in order to build capacity for the commercialisation of NHS research outputs, lead NHS Trusts, on behalf of partner regional Trusts, are bidding to the £10 million Department of Trade and Industry **Public Sector Research Establishment** fund. NHS Trusts and Department of Health bodies now have access to other Government funding schemes which support the commercialisation of intellectual property including University Challenge and the DTI Biotechnology Exploitation Platform Challenge Fund;
- working with **Regional Development Agencies** to ensure that NHS bodies work with **universities and industry** to support cluster and incubator development through access to Regional Innovation Funds; and
- supporting an **NHS Innovation Award**.

We recognise the need to identify how best to use NHS resources, and will therefore be developing a more strategic approach to innovation in the NHS over the coming year.

Information and communication technologies

2.22 Exploiting developments in information and communication technologies are also essential to effective health and social care services. Much of the reform and innovation necessary to translate the NHS Plan into practice will require best use of modern information and communication technologies. The Information for Health strategy has now been updated in Building the Information Core: Implementing the NHS Plan, (together with a more detailed on-line Update).

2.23 A major investment programme is in place to deliver the infrastructure needed to support improved IT systems in the NHS so that patients, clinicians, managers, researchers and other users can access the information they need. For example, now that almost all GP practices are connected to NHSnet, attention is focused on getting Trust-based clinicians connected in March 2002 and other NHS staff by March 2003, with access to e-mail, web-browsing facilities and a range of generic desktop tools. A range of knowledge-based services are now available online, e.g NHS Direct Online, National electronic Library for Health, nhs.uk. A significant programme is underway to develop the standards needed for Electronic Patient Records (organisation-based) and Electronic Health Records (patient-based longitudinal summaries), as well as the implementation of a number of national applications, such as the National Strategic Tracing Service, Human Resources/Payroll and Bookings, and clinical applications for example Rapid Access Chest Pain clinics. To underpin these, work is in hand to reprocore NHSnet by 2003, to address security and confidentiality issues, and to develop informatics skills.

2.24 The NHS Plan makes a number of references to the future use of **telemedicine and telecare applications** and we are funding a range of research underpinning these developments by evaluating the potential benefits from their use. This will inform moves towards optimising their uses in health care, and enable the drive towards the provision of more modern services.

2.25 **Digital Interactive TV (DiTV)** promises faster, easier access to health information for all and is likely to allow us to take a further significant step towards the NHS becoming an authoritative provider of information and advice on health at home and a proactive partner in helping people to change to healthier lifestyles. The Department of Health contracted with four broadcasting consortia to run pilot projects during 2001 and the early part of 2002 in order to explore a range of health applications of DiTV. There is also associated supporting work, including the development of a health information accreditation process to ensure quality of the information seen on TV, and an independent evaluation programme.

2.26 The NHS Plan indicates that smart cards for patients will be introduced, allowing easier access to health records. We are currently planning to fund a short scoping study, the objective of which is to provide a state-of-the art review of smart cards and to identify the issues that need to be researched in more detail. The Department is also committed to introducing **electronic prescriptions** by 2004 and is currently setting up a number of pilot sites which will be evaluated.

2.27 In common with other Government departments, the Department of Health has produced an e-Business strategy, which describes how over the next five years, the Department will develop electronic business methods to support its key objectives. The

strategy envisages a Department in three to five years time which has implemented much of the NHS Plan in a widely supported way, and underpins that by excellent ICT practice featuring:

- electronic communication as the main method of providing information to and communicating with all organisations and citizens through a wide variety of channels including websites, digital TV, cross-government portals, online discussion groups and email;
- working across Government and external organisational boundaries in virtual teams, and making these as equally possible as being physically co-located within the Department;
- interactive transactions with NHS and Social Care bodies, other Government agencies and independent organisations performed electronically in a co-ordinated way minimising the resources required;
- e-Business thinking embedded in policy and planning for new institutions and their operations;
- knowledge resources joined up and easily accessible to support evidence based policy and decision making.

Chapter 3

Supporting the science base in health and social care

Goal: To ensure that we work with our partners to sustain and develop the science base in health and social care

Promoting synergy in the science base for health and social care research

New NHS research and development funding system

Developing the research infrastructure in the NHS

Research capacity building

Supporting the science base in social care

3.1 The science base for health and social care relies on a partnership between Government, the NHS, the universities, industry and the voluntary sector: the **Higher Education Funding Council for England** provides infrastructural funds to university medical schools and other relevant departments; the **Medical Research Council** (MRC) and other Research Councils fund basic biomedical and clinical research; and the research charities are also a major investor. In addition to all this, industry funds a range of pre-competitive biomedical research in the universities. Alongside these bodies the Department of Health makes a substantial contribution to the science base infrastructure in health and social care research through support funding for R&D in NHS Trusts, the development of research infrastructure and investment in building research capacity, as well as funding specific research programmes. Promoting synergy between the different funders of the science base in health and social care is a key element in the Department's Science and Innovation Strategy.

Ensuring synergy in the science base for health and social care research

3.2 The Department of Health plays a major role in the science base for medical and health related research by funding support for R&D in NHS bodies and providers of NHS services. As well as providing for some directly managed research in the NHS, the support funding meets the costs to the NHS of providing the setting for high quality research led by the Research Councils and medical research charities. In medical/health research there is in effect a triple support system, with the Department providing the research infrastructure in the NHS for science alongside HEFCE, which provides the infrastructure funding for universities, and Research Councils who provide project funding. The Department therefore has a major stake in promoting synergy between the NHS and the science base. The Department places great emphasis on the need to work with other research funders to ensure that the science base for health and social care is adequately supported and the research agenda is effectively addressed, avoiding unnecessary duplication. These partnerships are critical to the achievement of the Department's science and innovation goals and have been formalised through a range of agreements.

3.3 The Department, together with the other UK Health Departments, has a series of of Concordats with all the **Research Councils** (except the Particle Physics and Astronomy

Research Council), the aims of which are to ensure the effective development, funding, management, dissemination and exploitation of publicly funded UK medical and health and social care research for the benefit of the population. The Concordats guarantee that the NHS will offer service support for research and development the Research Councils sponsor in the NHS.

3.4 The **medical research charities** are major players in healthcare research in the UK. The 1997 partnership agreement for non-commercially sponsored research in the NHS formalised arrangements for NHS support of charity-funded research. Under these arrangements the Department provides funding for service support costs for research funded by charities. Research and Development for a First Class Service: R&D Funding in the new NHS published in March 2000 announced revised arrangements for funding NHS service costs of work sponsored by funding partners that undertake to maintain defined standards. In April 2001 the Department published a Guide to collaboration in R&D between the NHS and other research funders which sets out the new arrangements by which non-commercial sponsors of R&D may become eligible for NHS Support for Science funding from 2002-3, through a bilateral agreement with the Department of Health or by co-funding with other sponsors who are themselves eligible.

3.5 The Department is also working more closely with specific charities to develop a more strategic approach to research in priority areas. Research funders forums have been set up in cancer, coronary heart disease and on research for older people. In cancer, this had led to the creation in April 2001 of a National Cancer Research Institute. See Box F for details.

3.6 The Department and HEFCE have established a Strategic Alliance to formalise working links and to support discussion and consideration of Department of Health and HEFCE R&D strategic objectives, priorities and activities to ensure the best use of public funds in supporting health and social care research. A number of Task Groups have addressed specific issues of common interest including the handling of health-related research in the Research Assessment Exercise (RAE), university-NHS links and the development of the research base for nursing and PAMS research. The Department has representatives on the RAE Fundamental Review Committee and on a number of Unit Assessment Panels.

3.7 As a consequence of its special role in relation to health research the Department of Health is a member of the **Science and Engineering Base Co-ordinating Committee** chaired by the Government's Chief Scientific Adviser and composed of senior representatives of the Education Departments and Funding and Research Councils.

New NHS R&D funding system

3.8 In March 2000, **Research and Development for a First Class Service: R&D funding in the new NHS** set out the Government's plans to develop a clearer and fairer system of NHS funding for R&D. It announced two streams of funding: **NHS Support for Science** and **NHS Priorities and Needs Funding**. The latter will provide funding for research of direct relevance to the NHS and is described in the following section. **NHS Support for Science** will meet the NHS costs of hosting R&D supported by eligible research funders, such as clinical trials sponsored by the Medical Research Council. The new system is designed to improve the efficiency with which these resources are allocated and clarify access to them. Work is in progress to develop formula-based allocations. The NHS will

meet these costs where agreed standards of strategic direction, mutual influence, open access and quality assurance are maintained by non-commercial research funders. A key element in the new funding system is to strengthen NHS-university partnerships. Under the new system universities will be treated as collaborative partners of the NHS in delivering high quality research, rather than as external research funders.

Developing the research infrastructure in the NHS

3.9 Improving the NHS infrastructure for research, particularly for clinical trials, is an area where the Department of Health can make a distinctive and crucial contribution to the science base for health research. We can make a key contribution to the science base, and at the same time facilitate innovation, by improving the infrastructure to realise the potential of the NHS as a unique test bed for research. This can be achieved through:

- horizontal national research networks in key topic areas to facilitate translational research and trials, following the model of the National Cancer Research Network;
- integrated/vertical research groupings to link basic scientific and technological developments with research into service delivery e.g. genetics knowledge parks; and
- better health informatics - improving access to information, developing new databases and other research resources e.g. genetics databases.

3.10 These approaches will form a platform to bring in players from industry and the science base on a collaborative basis to maximise opportunities for innovation and research. One particular area that will be developed is support for managed research networks in a priority area or clinical specialty. The Department has recently set up the National Cancer Research Network to improve the co-ordination of clinical trials and other well-designed studies in cancer care. The network aims to double the number of patients entering clinical trials for cancer in three years, in order to improve the speed with which new effective interventions can be brought to patients. It will also provide support for translational research to ensure the rapid development of advances in basic science into clinical interventions. The support provided by the Department of Health will allow clinical trials and other studies funded by Research Councils, charities and industry as well as the Department of Health, to be set up more quickly. A co-ordinating centre has been appointed to manage the network, which will be based on existing cancer care centres and networks. The Department is considering transferring this model to other clinical priority areas.

Research capacity building

3.11 Meeting the needs for health research requires a research workforce that encompasses a wide range of skilled researchers, from basic scientists to clinical researchers and health services researchers, including statisticians, economists and medical sociologists as well as healthcare professionals with research skills. While the research councils take responsibility for postgraduate training and capacity building in basic biomedical and clinical science, the Department of Health is taking the lead in co-ordinating strategy to secure the research capacity required to meet the needs for public health and health services research. We are working with the NHS, universities, Research Councils, HEFCE and other research

funders to define research capacity requirements in these areas and co-ordinate approaches to developing and sustaining this capacity. The Department will also be exploring with universities, funding partners and healthcare professions robust approaches to combining and promoting clinical and academic careers.

3.12 Department of Health support for research capacity building is delivered through a number of schemes [See Box D]. NHS R&D funding also gives support for local networks to improve the support for and quality of local research activity through, for example, providing expertise on statistical aspects of research.

BOX D - Research capacity

In order to deliver the research to meet the identified research needs, the Department of Health has recognised the need to develop the research workforce capacity. A **Research and Development Workforce Capacity Strategy Group**, has been established to address this area. The group is multi-disciplinary with representatives from many of the NHS professions and Department of Health.

Eight subgroups have been looking specifically at the capacity development issues of the different NHS disciplines and have provided guidance on various initiatives. These have included: Nursing; Medicine & Dentistry; Scientists & Technologists; Pharmacy; Public Health; Therapy Professions; Management; and other professions essential to health related R&D e.g. Health Economists, Statisticians, Medical Sociologists, Health Psychologists.

An example of initiatives includes the completion of a second round of the **Primary Care Awards Scheme**. A third round of these awards has been launched and now includes an additional post doctoral award, funded jointly with PPP Healthcare Medical Trust. The Department is collaborating with the MRC to jointly fund a **Primary Care Research Programme**. This represents a joint commitment of £12m to fund high quality primary care research, and the second round has just completed.

The Research and Development Workforce Capacity Strategy Group has been working with the Nursing Directorate in the Department of Health to follow-up recommendations on research in the Department's strategy for nursing "Making a Difference". A new Nursing Research Advisory Group will be established to assist with the development of a number of initiatives which may include a time limited national fellowship award scheme and plans to develop centres of research excellence. The Department and HEFCE have also set up a Task Group to consider how to build up high quality nursing research capacity in universities.

The Workforce Capacity Strategy Group is working through a number of external bodies, including HEFCE, professional organisations, the MRC and major charities to ensure appropriate systems are in place to build R&D capacity across the NHS. In particular the Department, working with HEFCE and charity funders, set up a **National Clinician Scientist Scheme** following the recommendations in the Savill Report on clinical academic careers.

The Department also launched a new **Public Health Career Scientist Scheme**, which is designed to attract high calibre individuals who have the potential to become the future leaders of academic public health. The scheme aims to:

- develop and enhance existing career opportunities in academic public health;
- provide funding to exceptional individuals who have demonstrated clear potential to become independent principal researchers and to lead research in their field in future;
- identify and nurture future academic leaders in public health; and
- develop collaborative partnerships with universities in response to identified research capacity needs.

Supporting the science base in social care

3.13 The Department is one of the biggest single funders in social care research. The research skills needed for social care research and social scientific and training needs are largely met by the **Economic and Social Research Council** (ESRC), but the Department also makes a considerable contribution by funding training awards in the social sciences to economists, statisticians and others. However there has been a longstanding shortage of research groups with expertise in research on social care issues. The Department has therefore invested in establishing and supporting a number of units with long term programmes of research on social care issues, for example, on community care and on children's services, to build up the knowledge base and research capacity in these areas and to take forward specific Department of Health research requirements when needed for policy. Support for these units is provided through the Department's Policy Research Programme. Continued investment in this way also makes a significant contribution to the science base, and universities are often partners in funding these units.

3.14 The Department of Health acknowledges the very helpful role of the ESRC in working with the science base to provide capacity, expertise and programmes of research, which complement the work of the Department. For example, the programme of work which examines the social aspects of innovative technology in health care, and a programme which is making a major contribution to our understanding of inequalities in health.

Chapter 4

Knowledge generation for health and social care

Goal : To ensure that policy and practice in health and social care are based wherever possible on sound science and research

Identifying priorities for research

Delivering research

Current priorities

4.1 The Department of Health needs research to ensure that policy and practice in public health, health care and social care is based on reliable evidence of needs and of what works best to meet those needs. The Department draws widely on national and international research to inform policy and practice. It also invests in research to support its objectives, and priorities within the research agenda are driven by policy and service priorities.

Identifying research priorities and needs

4.2 The main drivers shaping the Department's research priorities are the need to address issues which are of public health concern and the need to ensure that policy and service delivery are based on well founded evidence. Research requirements are identified through a number of different routes. Research and development staff in the Department work closely with their **policy customers** to identify the research required to support Department of Health priorities and deliver objectives, drawing on systematic reviews of research and expert advice. In a number of priority areas the Department has appointed National Clinical Directors (Tsars) and Task Forces to drive the NHS Plan commitments and National Service Frameworks' requirements forward; the Department's R&D staff are working closely with the Tsars and Task Forces to identify research needs. The National Institute for Clinical Excellence and the National Screening Committee also act as customers for Department of Health research. **Expert Advisory Committees** including Scientific Advisory Committees, research funders and other topic review groups, also play a role in identifying research gaps and requirements groups in priority areas. The Department will be introducing a system of strategic reviews to inform future research requirements in NHS priority areas.

4.3 The Department of Health also identifies research opportunities and needs arising from scientific and technological developments. **Horizon Scanning** is used to identify clinical innovations on which the NHS will need evidence based advice, and involve a wide trawl of professional bodies, Research Councils, the NHS, researchers, interest groups and the public. The Department of Health funds the National Horizon Scanning Centre (NHSC) at the University of Birmingham to carry out this work, who provide advance notice of new and emerging technologies that might require urgent evaluation, consideration of clinical and cost impact, or modification of clinical guidance. The scientific and technological opportunities relevant to healthcare identified by **Foresight** also feed into priority setting processes.

Box E – example of Foresight programme

Foresight Estates was established in 1999 as an Associate Programme of the national Foresight programme. Its aims were to envisage the future for the healthcare built environment and harness technology to achieve our goals and forge new links and partnerships. Foresight Estates has helped clarify a number of options and will continue to contribute to the development of the business plan.

4.4 The Department engages with a wide range of external **stakeholders** through consultation exercises, nationally and locally, about user needs for research using a variety of methods. Recent examples include a listening exercise involving a series of focus groups with a range of patients, carers, professionals and other stakeholders to identify research needs for the Service Delivery and Organisation Programme. Specific systems for identifying research needs engaging professionals, managers, the voluntary sector and interest groups, are used by the Health Technology Assessment Programme.

4.5 High level co-ordination of research priorities is currently provided through the Departmental Research Committee, which reviews overall priorities for all Department of Health R&D, and the NHS Central Research and Development Committee, which provides strategic input on NHS R&D. We will be reviewing these arrangements as health and social care policy-making in the Department of Health are brought more closely together.

Delivering research

4.6. The research programmes and initiatives taken forward by the Department reflect a mix of priorities and needs identified through the routes outlined above. The Department works in a number of ways to ensure that research is available to address priorities and needs. Methods include:

- accessing **national and international research**;
- **working in partnerships** with and influencing other funders;
- running **directly commissioned research programmes**;
- supporting high quality research programmes in **NHS providers**; and
- research supported through **Non-Departmental Public Bodies**;

National and international research

4.7 The Department of Health accesses findings from national and international research through a range of sources including Scientific Advisory Committees, advisers, professional staff, databases and reviews. The Department is increasingly commissioning systematic reviews of research to provide an analysis of the knowledge base on specific topics. These reviews inform policy thinking, help identify gaps where further research would be useful and feed into decision making for local and specialist services in the NHS.

Working in partnerships with other funders

4.8 Where the research needs identified are likely to require more basic scientific input, the Department will look to the Research Councils to take work forward. The Health Departments' Concordats with the Research Councils formalise this relationship. Interactions of this kind occur most often with the Medical Research Council and to reflect this

there is a formal framework for recording Department of Health (and other Health Departments) priorities for MRC research. In some cases the Department will ask the MRC to take research forward proactively, for example in Creutzfeldt Jakob Disease, and sometimes do so with Department of Health R&D funding, for example on HIV/AIDS epidemiology.

4.9 Many of the public health policy issues the Department has to address involve other Government departments' interests. In these areas we will often work jointly with them to commission research, for example, the Department, the MRC and the then Department for Environment, Transport and Regions jointly funded a programme of research on air pollution. In some areas, industry is also a partner e.g. in the new programme of research on mobile phones and health.

4.10 Increasingly, the Department is working with a range of other Government and non-government funders through formal Research Funders Groups, for example in Creutzfeldt Jakob Disease and in cancer. This helps to ensure that the full range of research needs are properly addressed and the best use is made of available resources.

Directly commissioned research programmes

4.11 Though there are a number of other research funders in health and social care, they operate largely in responsive mode and are likely to be driven more by science push than policy pull. While such work is essential to our wider knowledge base for health and social care, many of the research needs identified for policy and practice have to be met directly by the Department. The Department of Health has therefore developed a number of generic programmes through which research is delivered to meet research needs. Overall the Department of Health spends over £100 million per annum in total on directly commissioned research programmes.

4.12 The Department supports **National NHS R&D Programmes** through which NHS research priorities and needs are met. The principal programmes are:

- the **Health Technology Assessment (HTA) Programme**, which meets the need for high quality research information on the costs, effectiveness, and broader impact of health technologies, and which has strong international links; and
- the **Service Delivery and Organisation (SDO) Programme**, which focuses on the organisation and delivery of services to improve patient care.

4.13 The Department of Health also funds a **Policy Research Programme** to support its work across the whole range of Secretary of State's responsibilities in public health, health services and social care. The programme supports a mix of longer-term programmes in research units, initiatives on specific themes, individual projects and reviews. Sufficient flexibility is retained within the budget to enable urgent in-year research needs to be taken forward. Criteria for prioritising calls on the budget are:

- relevance to the priorities, aims and objectives of the Department of Health in improving the health and social welfare of the population and reducing inequalities;
- size and importance of the problem to be addressed in terms of actual or potential burden of disease or social condition;

- well-defined plans for introducing research results into current policy activity or the formulation of future policy;
- timeliness;
- feasibility of research;
- likely return on the investment in research in terms of impact on health, and other benefits; and
- appropriateness and availability of other research budgets, for example, those of Non-Departmental Public Bodies, Research Councils, NHS R&D.

4.14 Department of Health/NHS R&D Programme Directors and Portfolio Directors (research leads on key priority areas) meet regularly to ensure prioritised research needs are channelled through the appropriate programmes.

4.15 The Department of Health also manages a number of other smaller research budgets either on specific programmes e.g. Radiation Protection Research, or on an ad hoc basis. A number of the Department's agencies also have R&D programmes, e.g. NHS Estates.

High quality research programmes in NHS providers

4.16 Much of the research needed for better health and social care services is carried out in the NHS. As well as funding and setting the overall strategic direction for research, the Department has a responsibility to ensure that the NHS works effectively to deliver high quality research.

4.17 As part of the new **NHS Priorities and Needs** funding arrangements, we will be promoting research partnerships and networks between the NHS, researchers and consumers, to meet the needs for health and health care research. Programmes of research in NHS and partner research organisations will be supported directly. The Department may specify such programmes in detail or may agree a strategic direction for the organisation, collaboration or network with delegated authority to determine how best to deliver the desired outcomes.

Non-Departmental Public Bodies/Arm's length bodies

4.18 As part of their wider responsibilities, a number of Department of Health sponsored arm's length bodies carry out research, as well as surveillance and specific activities designed to meet the Department's needs in protecting public health from the threat posed by communicable diseases and other agents. Currently these are:

- **Public Health Laboratory Service (PHLS);**
- **National Institute for Biological Standards and Control (NIBSC);**
- **Centre for Applied Microbiology and Research (CAMR) and**
- **National Radiological Protection Board (NRPB)**

4.19 They each have a five year corporate plan, which is reviewed annually, ensuring that it is consistent with the Department's priorities.

4.20 Between them, these bodies represent a unique resource. They each have a substantial research commitment, especially CAMR, which derives about half of its income from commercial activities although the majority of its R&D is to meet defined Department of

Health customer objectives. All these bodies are committed to developing and using the most effective technologies to meet their aims and objectives, and the Department encourages appropriate exploitation of research they undertake to meet their aims.

4.21 The Department of Health also funds the **Health Development Agency** to improve the health of the public. Part of its role is to put together the evidence base on what works to improve health and make the latest research and best practice available on-line. This complements the primary research on health promotion taken forward by the Department through its Policy Research Programme.

R&D procurement and research management

4.22 The Department of Health, unlike some other Government departments, does not conduct research in-house, but places contracts with universities and outside organisations in addition to the NHS and Non Departmental Public Bodies to carry out the research. Once priorities have been identified the research is generally put out to tender and contractors are appointed through open competition. Advertisements are placed in the national press and details of tenders are available on the Department of Health R&D website. Independent peer review is central to all stages of the Department's research process. During the commissioning of research individual proposals are peer reviewed and commissioning panels of experts are used for large programmes. Research reports are subject to the peer review process, with comments fed back to lead researchers and incorporated into the final reports.

4.23 Research funded by the Department of Health is actively managed. For projects commissioned through the Policy Research Programme, liaison officers in the Department provide detailed management with input from policy customers and, where appropriate project advisory committees. In the NHS R&D Programmes, the Programme management teams regularly monitor research projects as they progress. In line with contractual requirements lead researchers are required to submit six monthly progress reports on projects, and in some larger projects a member of the Department or the Programme Management team will attend Advisory Group meetings.

Current Department of Health R&D priorities

4.24 Department of Health R&D priority topics for directly commissioned programmes are currently:

- **genetics;**
- **cancer** to support the NHS Cancer Plan and NHS Prostate Cancer Programme;
- **coronary heart disease, mental health, older people, children's health and services**, to provide an evidence base for, and help implement and evaluate aspects of, National Service Frameworks (NSF). Other topics will be added to this list as the NSF programme rolls forward;
- **systematic reviews and health technology assessments** to meet the needs of the National Institute of Clinical Excellence (NICE) as it develops appraisal guidance, guidelines and other advice on clinical policy in the NHS;

- evaluation of the implementation and impact of the **quality** agenda in **health and social care**, including improving access to services, new primary care services, services for people with physical and learning disabilities, as laid out in the NHS Plan;
- improving the evidence-base for a range of **public health policies**, including Creutzfeldt Jakob Disease, **HIV/AIDS** and **inequalities in health**, to support the implementation of Saving Lives: Our Healthier Nation;
- extending the evidence base to support **Human Resources** policy and practice **in the NHS and social care**;
- evaluating ways of increasing **patient participation** in decision-making;
- evaluation of new NHS service developments using **information and communication technologies**, including telemedicine;
- analytical work to support the review of **NHS resource allocation**; and
- developing an evidence base to inform **patient safety**.

4.25 For details of the cancer, public health and older people research priorities see boxes F, G and H. Details of the genetics research and development strategy are provided in box A in chapter 2.

4.26 As part of the Concordat with the Medical Research Council, UK Health Departments indicate areas to which they would like the MRC to give priority. These currently include broader strategic priorities for biomedical research, genetics, cancer, coronary heart disease, mental health and other service and policy priorities but also specific topics where the research expertise required is more appropriate to MRC; these currently include antibiotic resistance, Creutzfeldt Jakob Disease, HIV/AIDS.

4.27 Research priorities for the Non Departmental Public Bodies are set out in Box I.

BOX F - Cancer research

Cancer services are a major priority for the NHS. The **NHS Cancer Plan** sets out the blueprint for the future of cancer services: with increased investment in the cancer workforce, equipment and drugs; with improvements in prevention, screening and palliative care; and with challenging targets for reducing smoking and reducing waiting times for all stages of the cancer pathway. As a result of this investment and reform it is expected that by 2010 five-year survival rates for cancer will compare with the best in Europe.

Cancer research is essential to improving cancer outcomes. Laboratory research helps us to understand the genetic and cellular changes that may produce cancer. Genetic research will provide us with opportunities not only for identifying people at risk of getting cancer but also for developing improved diagnoses and treatments. Epidemiological studies are required to identify the causes of cancer, clinical trials are needed to find better ways of screening for cancer and improving cancer care, and health services research is needed to help improve the organisation and delivery of cancer care.

Together with the wider investment in the science base by the Government, the Department of Health is targeting increased investment in cancer research. By 2003 an additional £20 million each year will be invested in the infrastructure for cancer research, as well as an extra £4 million on prostate cancer research.

The Department is also leading in developing a more strategic approach to cancer research across all funders. The **Cancer Research Funders Forum** (CRFF) was established in 1999 to help improve the co-ordination of researchers. The CRFF includes the Department of Health, the Medical Research Council, the Cancer Research Campaign, the Imperial Cancer Research Fund, the Leukaemia Research Fund, the Ludwig Institute and Marie Curie Cancer Care.

To improve the co-ordination of clinical trials, translational research and other well-designed studies, the Department has set up the **National Cancer Research Network**. The Network aims to double the number of patients entering clinical trials within 3 years and will map on to the cancer service networks around the country

Following the publication of the House of Commons Science and Technology Committee report on cancer research, the Department of Health's Director of Research and Development and the National Cancer Director were asked by Department of Health Ministers to consult all those involved in the funding and management of cancer research with a view to bringing forward definitive proposals for a **National Cancer Research Institute** (NCRI). The NCRI has now been established and will provide the focus for cancer research conducted across the country, and will provide strategic oversight of that research. It will take the lead in identifying areas where further research initiatives are indicated and are most likely to lead to progress. The NCRI is a partnership between the Government, the cancer research charities and the pharmaceutical industry

The Department is also supporting specific programmes of research on cancer screening, prostate cancer, childhood cancer and a range of issues on access to and delivery of cancer services. Further work will be taken forward on epidemiology, prevention, screening, genetics, primary care and palliative care as part of future cancer research strategy.

The Department recognises that the NHS must make the best use of the results of cancer research. It is a founding and major funder of the Cochrane Collaboration, which contains over 50 systematic reviews related to cancer. In addition evidence-based reviews to inform the Improving Outcomes guidance on cancer services have been supported and reviews will be commissioned to ensure the most recent evidence informs guidance from the National Institute of Clinical Excellence.

BOX G - Public Health and inequalities in health

Improving public health and reducing inequalities in health is a major priority for the government.

Ministers have recently agreed a new Public Health R&D Strategy, developed across all major contributing funders in Government departments and Research Councils, which aims to ensure more relevant public health R&D, carried out on a better multi-disciplinary basis, based on better information and ensuring greater accessibility of findings. The Department of Health's Policy Research Programme provides a major element of this strategy and is currently undertaking research in the following areas to support policy development and the delivery of Departmental objectives:

Encouraging people to live healthy lives by improving diet and lifestyle, and inequalities in health

- Inequalities in Health
- Nutrition
- Health Promotion
- Alcohol
- Smoking
- Drug Misuse
- Teenage Pregnancy
- Sexual Health (including HIV/AIDS)

Protection of the public from diseases caused by a range of pathogens

- Communicable diseases, Creutzfeldt Jakob Disease and Hepatitis C
- Vaccines
- Hospital acquired infection and antimicrobial resistance

Improving health by understanding wider environmental impacts on health

- UV radiation and skin cancer
- Air pollution and respiratory disease
- Health effects of indoor and outdoor pollution
- Other environmental exposure to chemicals and radiation
- LINK programme with industry on mobile phones and health
- Health effects of noise
- Health effects around landfill sites
- Understanding the impact of the actions of Government and its agencies on these health related environmental factors

New medium term priorities for research on public health issues are currently under discussion.

BOX H - Older People

Health and social care services for older people are one of the Government's priority areas. In March 2001 the Department published a National Service Framework (NSF) to set standards and requirements for these services. A research strategy is being drawn up to support the implementation of the NSF for older people. The strategy aims to:

- Ensure the right amount of research takes place to support the development of older people's services;
- Develop the knowledge base on older people's services and make that knowledge accessible to clinicians, practitioners, managers, service-users and other making decisions about health and social care for older people;
- make the research agenda more responsive to the needs of older people and their carers and decision-makers and involve them in research, where appropriate;
- encourage the development and evaluation of innovative practice in health and social care;
- support research which will help reduce disability and the need for long-term care by maximising independent living and social functioning and improving rehabilitation services;
- enhance the well-being of older people and their family and carers; and
- inform the choices of individual users of health and social care services.

Developing and implementing this strategy is being done through:

- an Advisory Network of scientific experts and researchers in a wide variety of disciplines as well as those using findings of research to improve clinical decisions and service delivery for older people;
- a Directed Portfolio of research on older people. The Research Portfolio Director will work with the National Director for Services for Older People and take account of research that has implications for older people in other areas;
- a Funders Forum on Ageing Research. A national forum of key funders of research on health and social care related to older people has been established and will meet twice a year. The Forum's overall aim will be to stimulate and facilitate multidisciplinary working and develop research activities across the boundaries between research funders.

Immediate research priorities for older people's services include:

- a longitudinal study of ageing which will cover a representative sample of about 13,000 people aged 50 and over and will collect information on health, economics and social networks;
- an evaluation of intermediate care. The development of intermediate care is a key part of the wider programme to improve services for older people. The evaluation will be independent and will assess the quality, effectiveness and costs of a variety of services to reduce avoidable hospital admission, promote timely discharge and rehabilitation, and minimise dependence on long term care;
- a programme of research on Continuity of Care assessing the impact of continuity of care, or lack of it, on patient outcomes. This will make an important contribution to improving the quality of services for older people;
- building on the existing programme of research on social care relevant to older people to answer basic questions about the need for, and access to, services as well as ways of improving care management and the costs of domicilliary, residential and nursing care. The research will focus on outcomes and user and carer perspectives;
- research arising out of the Government's response to the Royal Commission on Long Term Care which will include research on the cost-effectiveness of rehabilitation and intermediate care and longitudinal data to inform policy; and
- research to modernise hearing aid services.

BOX I - R&D Priorities for Arms Length Bodies (ALBs)

Each of the Arms Length Bodies (ALBs) associated with communicable disease (i.e. PHLS, MRA and NBSB) has a research programme, designed to support its goals and objectives. For all of these bodies, the future priorities will be based on currently foreseeable developments, but the nature of communicable diseases is such that determination of priorities is likely to be driven by external factors. In the medium term, this area will see dramatic changes arising from the application of biotechnology, nanotechnology and information technology. All of these bodies collaborate on R&D in areas where their expertise and interests are complementary.

At the **Public Health Laboratory Service** (PHLS) priority areas for 2001/02 include antimicrobial susceptibility, bacterial respiratory infections (e.g. tuberculosis), meningococcal surveillance, vaccine development and evaluation, and new molecular diagnostics. All these areas will continue to feature in future priorities but the PHLS has to remain responsive to emerging and re-emerging infections and to adapt its programmes accordingly. Approximately half of the R&D carried out by the PHLS is funded by external sources, most of which is peer-reviewed grant funding.

The **Microbiological Research Authority** (MRA), through the **Centre for Applied Microbiology and Research** (CAMR), has a research strategy aimed at maintaining an appropriate R&D capacity to support current and future Government needs in microbiological risk assessment and in responding to dangerous pathogens. The Department of Health funded element of research at CAMR is directed by a Research Steering Group, which advises the Department of Health and assists in reviewing the progress and outputs of these projects. CAMR also seeks to generate income from external sources through development of intellectual property as the basis for partnerships with the private sector and through manufacture and supply of specialist biotechnology products and vaccines.

The **National Institute for Biological Standards and Control** (NIBSC) is the executive arm of the **National Biological Standards Board**, which has the remit of assuring the potency, purity and related efficacy and safety of biological substances used as human medicines. Due to its unique international role in the assessment of biological medicines, research carried out at NIBSC is recognised in many important areas including research into AIDS vaccines; the study of bacterial vaccines; the development of influenza vaccines, including possible pandemic vaccines; and, more recently, research into transmissible spongiform encephalopathies and into gene therapy. NIBSC has also brought international groups together to work on particular problem areas such as DNA vaccines; testing of blood for viral contamination; and cell and tissue therapy. With the increasing importance of genetic testing and the new biological products which will be developed as the result of mapping the human genome, NIBSC will be expected to provide expertise, standards and methodology in many emerging areas. A significant proportion of the R&D at NIBSC is externally funded.

The **National Radiological Protection Board** (NRPB) provides an independent, impartial and authoritative source of scientific advice on questions related to health effects from ionising and non-ionising radiations and carries out research and development work to underpin this advice. Key issues and objectives to be addressed in the coming years are expected to include concerns related to exposures to an increasing range of sources of electromagnetic radiations from telecommunications and other new technologies; the provision of improved information on exposures to ultraviolet radiation from solar radiation and artificial sources and on methods of protection; the need to understand better the health consequences of exposure to low levels of ionising radiations, whether they arise from medical uses, from occupational exposure or as a result of radioactive materials in the general environment; the development of knowledge on variations in sensitivity to ionising and non-ionising radiations within the population as a consequence of hereditary or other factors; providing an improved understanding of the transfer of radionuclides through the terrestrial and aquatic environment; and the development of techniques for assessing doses and risks to patients from medical exposures.

Chapter 5

Knowledge management in policy and practice

Goal: To ensure that policy and practice in health and social care are based wherever possible on sound science and research

Utilising science and research in policy making

Improving knowledge management to promote the use of science and research in health and social care practice

5.1 Previous chapters described the Department's strategy for identifying and prioritising needs for scientific and research work and for ensuring these are met. This chapter describes strategies for ensuring that knowledge from science and research around the world is available to, and used by policy makers, decision-makers and practitioners in health and social care services and the public.

Utilising science and research in policy-making

5.2 Science and research have formed the basis for policies in the Department of Health for many years, and mechanisms for identifying and incorporating scientific knowledge and advice into policies are well developed. The Department currently obtains scientific advice from:

- expert Advisory Committees set up by the Department (which vary in size and constitution according to their remit);
- in-house and Departmental Agency professional staff, who are sometimes national or international experts themselves, and who have a wide range of outside professional contacts;
- staff of certain Non-Departmental Public Bodies e.g. the Public Health Laboratory Service and the National Radiological Protection Board;
- outside individuals, who may be selected ad hoc or who may have been previously appointed;
- outside bodies, e.g. professional associations.

5.3 The Department of Health currently manages over 25 Scientific **Advisory Committees** on issues ranging from vaccination and immunisation to the medical effects of air pollution who advise the Chief Medical Officer or Ministers.

BOX 1 - an example of a Scientific Advisory Committee feeding into policy

The Advisory Committee on Dangerous Pathogens (ACDP) provided an independent risk assessment of the health risk associated with changing quarantine rules for movement of pet dogs/cats from rabies-free areas. This advice became embodied in the legislation for the Pet Travel Scheme.

5.4 The Department is continually working to improve the way it seeks and acts upon scientific advice and to ensure that it follows best practice and guidance from the Government's Chief Scientific Adviser. Initiatives include:

- a comprehensive internal review of how the Public Health Group in the Department of Health obtains scientific advice;
- co-funding with other departments a study to identify good practice in managing scientific advice, which was completed last year. Many Department of Health Advisory Committee members, including lay people, volunteered to take part in this study;
- funding research to evaluate different methods of public participation in the advisory process; and
- participation in cross-Whitehall initiatives on risk assessment and decision making.

5.5 The Department of Health is also considering ways of making further improvements, following publication of the **BSE Inquiry (Phillips) Report and Guidelines 2000**, particularly in the areas of openness, communicating with the public, risk management, handling scientific uncertainty and application of the precautionary principle. Recent activities include:

- new research on expert processes and how we might handle a future BSE-like problem;
- funding the Human Genetics Commission to investigate ways of communicating with the public, including open meetings and consultation exercises; and
- in-house training programmes for staff on managing and communicating risks better.

5.6 Research findings from **Department of Health funded research programmes** are fed to policy customers directly or through advisory committees, depending on their purpose, for example whether they are being used to inform policy advice for Ministers or being fed into the development of guidance or National Service Frameworks. The National Screening Committee which provides advice on NHS screening policy is also a major user of Department of Health funded research. Work funded through the Health Technology Assessment Programme is fed directly to the National Institute of Clinical Excellence to inform their appraisals of healthcare interventions on which they base advice to the NHS. See Box K for examples.

5.7 The Department also makes extensive use of systematic reviews of research which pull together research relevant to particular issues, drawn from published research sources, to feed into Departmental policy making and service development.

BOX K - Health Technology Assessment (HTA) and National Institute of Clinical Excellence

The new quality agenda in the NHS including clinical governance, National Service Frameworks, and the National Institute for Clinical Excellence (NICE) has placed increasing demands on the HTA programme to deliver the evidence that the NHS needs. In particular, NICE - because it requires assessment of many of the techniques upon which it gives guidance or guidelines to the NHS - perhaps had the greatest interaction with the HTA programme. It has done so partly because the HTA programme is well placed to advise on the topics where guidance is most needed, and partly because NICE can lend considerable weight to the implementation of recommendations that emerge from health technology assessments. But part of the impact on HTA has also been because NICE needs a faster turnaround of the evidence than the full systematic reviews that HTA has been required to provide so far. Thus NICE has necessitated a new HTA product, the Rapid Reviews now being produced at the rate of about 40 per year.

NICE has issued guidance based on reviews commissioned by the Health Technology Assessment programme in the following areas:

DENTISTRY

- removal of wisdom teeth

ORTHOPAEDIC/ ELDERLY

- hip prostheses
- treatment of cartilage defects in knee joints

CANCER

- taxanes for ovarian cancer
- taxanes for breast cancer
- liquid based cytology for cervical screening

CORONARY HEART DISEASE

- coronary artery stents in the treatment of heart disease
- treatment of unstable angina
- management of obesity
- implantable cardioverter defibrillators for arrhythmias

MENTAL HEALTH

- treatment of Alzheimer's disease
- riluzole for the treatment of motor neurone disease

CHRONIC DISEASE

- pioglitazone in the treatment of diabetes
- combination therapy for chronic hepatitis C
- inhaler systems for childhood asthma

TREATMENT OF COMMON ILLNESS

- treatment and prevention of influenza

Improving knowledge management

5.8 The Department is also concerned to promote better knowledge management in health and social care services. An effective knowledge management strategy in the NHS and social care would result in all staff having access to the information they need to do their work including knowing where to get advice, access evidence-based research and how to share best practice and experience with colleagues.

5.9 There is still considerable scope within the Department of Health, the NHS and social care for improving knowledge management and transfer, to reach not only policy makers but also healthcare decision makers and practitioners and the public. This involves three key aspects:

- making knowledge accessible to decision makers in the course of their work;
- motivating decision makers to seek knowledge and then use it; and
- skilling decision makers to find knowledge and incorporate it into their decisions.

Making knowledge accessible

5.10 The Department has championed the **open publication** of research findings in relation to its research contracts for some considerable time. Research projects are funded with the expectation that the results will be published. Once peer review is successfully completed, encouragement is given to researchers to make their work widely available, using a number of dissemination routes.

5.11 The Department's **research and development website** has information on the various research programmes and provides access to the following tools, which have been designed to disseminate ongoing and completed research.

5.12 The Department of Health has set up the **National Research Register (NRR)** which includes information on ongoing and recently completed research projects on health and social care. Information is held on over 80,000 research projects and is expected to grow further, as well as entries from the Medical Research Council's Clinical Trials Register, and details on reviews in progress collected by the NHS Centre for Reviews and Dissemination. The register can help to:

- identify unpublished research - particularly important to systematic reviewers of research;
- provide early warning on research which may lead to important research findings;
- identify and bring together researchers between and across related areas of research; and
- avoid unnecessary duplication in research - a waste of resources as well as potentially unethical.

5.13 More recently the Department has set up a **Research Findings electronic Register (ReFeR)** which is a freely available database, providing 'prompt sight' of the findings of completed research funded by the Department on health and social care. ReFeR contains summaries of research findings from single 'primary' research studies as well as systematic reviews of primary studies. The register presents a brief summary of information from research studies together with 'signposts' to fuller information, including published articles.

5.14 The Department supports the **UK Cochrane Centre** whose purpose is facilitating and co-ordinating reviews primarily in the specialised area of randomised controlled trials of health care. The Department also funds the **Centre for Reviews and Dissemination** (CRD) which commissions and supports experts to undertake specific systematic reviews in areas of priority to the NHS, provides an information service for those interested or involved in undertaking systematic reviews, and maintains the Database of Abstracts of Reviews of Effectiveness (DARE) which contains about 1600 abstracts and the NHS Economic Evaluations Database (NHSEED) with around 2000 economic evaluations of health care interactions. CRD also provides information on healthcare interventions specifically for patients. The Department also funds the Health Development Agency and the Institute of Education at London University to provide reviews of evidence in the field of public health.

5.15 The Department has negotiated central purchase of the British Medical Journal publication **Clinical Evidence**, a compendium of best available evidence for clinical practice, to distribute widely throughout the NHS. **National Service Frameworks** and **NICE** guidance also provide evidence-based advice to the NHS. A **Centre for evidence-based social care** has also been set up to encourage the use of evidence in planning and delivering social services. The Department will provide the reviews to underpin the work of the new **Social Care Institute of Excellence**.

5.16 The Government's Information Strategy for the NHS announced the intention to introduce a **National electronic Library for Health** (NeLH) by March 2002. The NeLH is being developed by the NHS Information Authority. The role of the NeLH is to provide health care professionals and the public (through NHS Direct Online and the New Library Network) with knowledge and know-how to support health care related decisions.

Box L - National Electronic Library for Health (NeLH)

The Library will:

- provide easy access to best, current knowledge and know-how;
- improve health and healthcare, clinical practice & patient choice; and
- support communities of practice by facilitating access to specialist evidence and linking researchers, clinicians and patients.

The NeLH will be available via NHSnet and the Internet. It may be thought of as being organised on three floors:

- know-how,
- knowledge,
- knowledge management and health informatics.

There is also an atrium where users can find the help desk for their special interest and where there is an opportunity to share ideas with other members of their profession. NeLH is developing partnerships with NHS library services, NHS Direct Online, a developing National electronic Library for Social Care and libraries in higher education to improve co-ordination of and better access to knowledge, library and information services to meet the needs of clinicians, patients and the public.

5.17 The **National Electronic Library for Social Care** has also been established. A comprehensive database of the key best practice, guidance, standards and research review publications across the whole of social care is being developed. The intention is to assist those planning, delivering and monitoring services to ensure that practice is based on the best available evidence, and is meeting current guidance and standards required.

Motivating decision makers

5.18 New accountability and monitoring arrangements for care in the NHS should help motivate decision makers to seek knowledge and use it. The introduction of clinical governance and the duty of quality, together with greater monitoring of the quality of NHS services through the **Commission for Health Improvement** (CHI) and regular checks on individual competence, will drive greater demand for and use of the evidence base for effective health care. This will need to be supported by training in critical appraisal skills. A number of evidence-based medicine centres have already grown up, through both national and local funding to encourage and support the greater use of evidence in clinical decision-making.

5.19 However, there is still much to be done along the knowledge management path in terms of working practices and cultural change, and in particular to support the gathering and sharing of intangible or implicit knowledge. Initiatives being developed and evaluated include:

- knowledge harvesting (the systematic gathering of tacit knowledge from individuals who have been identified as holding expert or unique knowledge);
- action learning sets, breakthrough collaboratives and communities of practice;
- incentive and reward schemes e.g. building knowledge sharing into core performance targets; and
- processes such as digital archiving and electronic records management to preserve and make accessible the corporate memory.

Skilling decision makers

5.20 The skills in finding, appraising and using research evidence mentioned above are only part of the skill set required for effective knowledge management within health and social services. Knowledge management also requires skills in information analysis and management, computer technology, and communication. The education and training strategy of the Information for Health Strategy emphasises basic computer literacy as a core competency for knowledge management. NHS staff will be encouraged to enrol for the European Computer Driving Licence as part of this programme to improve their skills in using information systems to obtain clinical and managerial knowledge.

5.21 Knowledge management is also being recognised as a core competency for new health care professionals. For example knowledge management is a core part of the curriculum in the New Generation Programme, a multidisciplinary undergraduate health care programme at Southampton University. This programme includes knowledge and information management modules which are being developed in such a way that they can support continuing professional development for NHS staff.

Chapter 6

Protecting and involving the public

Goal: To ensure that the health and safety of the public and patients is protected and their interests reflected

Risk Assessment

Regulation and patient safety

Patient confidentiality

Research governance

Involving consumers in research

6.1 Previous chapters have described the Department's strategy in supporting science and innovation, investing in research and providing scientific advice. We also have a role alongside other Government departments in protecting patient and public safety in relation to new products and potential hazards to health arising from scientific developments and new technologies. In addition we have responsibility for ensuring patient interests are protected in the conduct of research and that patients and public interests are played into research and the scientific advisory system.

Risk Assessment

6.2 In its role of protecting the public from a range of potential health hazards, the Department takes advice from a number of Scientific Advisory Committees. A key task for the Committees and for the Department of Health is to provide an assessment of the level of risk associated with a potential hazard, to inform both public policy and private choices.

6.3 As part of wider Government strategy in this area the Department is committed to improving the way it manages risk and uncertainty in relation to public health. The general approach to risk is to make available to people sufficient information about a risk in a form that is easily understood and to respect the need for choice by the individual. However, where, for example, the risks are taken involuntarily, affect particularly vulnerable groups, such as children, or where the hazard is widespread, the public expects Government to ensure that measures are in place to protect their health. We also need to deal with issues where people perceive possible risks to health, but where the scientific evidence of harm is inconclusive. A balance needs to be struck between intervening too much and stifling people's freedom of action or failing to help protect them sufficiently from actual or potential hazards. However this balance is struck, the aim must always be to make the reasons for risk management decisions clear to Parliament and the public.

6.4 The Department is developing its risk management framework (the principles and key steps for which were set out in *Saving Lives ; Our Healthier Nation*). The Department has introduced better training for policy-makers on issues such as the precautionary approach, the scientific advisory process, public perception and understanding of risk issues and the role of the media. This training has commitment from senior management and personal input from the Chief Medical Officer.

6.5 The Department is commissioning research, some in collaboration with other departments, to ensure a better understanding of public perceptions and reactions to risk

issues. We are also investigating ways of achieving greater public involvement in the risk analysis process. Examples include research on:

- the social amplification of risk (i.e. some risks scare people while larger ones do not);
- public participation methods (e.g. focus groups, consensus conferences, citizens juries);
- risk literacy and ways of improving public understanding of health risks; and
- exploring ways that Scientific Advisory Committees might communicate with the public e.g. holding open meetings of the Human Genetics Commission and public consultation exercises.

6.6 Through the **Inter-departmental Liaison Group on Risk Assessment** (ILGRA), and its subgroup on risk communication, the Department of Health is contributing to better sharing of information between Government officials and a more consistent approach to risk across departments.

Regulation and patient safety

6.7 In relation to the introduction and use of new pharmaceutical and medical devices products, the Department plays a direct role in their approval and monitoring through its agencies - the **Medical Devices Agency** (MDA) and the **Medicines Control Agency** (MCA). The MDA is responsible for the regulation and oversight of the safety of medical devices on the UK market and the MCA is responsible for licensing medicines and medicines control. The strategic objectives of the MDA and the MCA are laid out in their published plans.

6.8 The MDA has a major role in assuring consumers that the highest possible standards of safety are being adhered to, so that consumers, principally in the NHS, can be confident in purchasing often highly innovative devices. The MDA is the regulatory Competent Authority under the various European Directives for medical devices. The MDA has been and will continue to be a major player in the negotiation and development of these New Approach Directives, which are seen as a relatively light touch approach to regulation. But when, as at present, there is a need to reinforce the protection of public health in certain areas, the MDA will continue to press for change within Europe.

6.9 As well as consultation with the independent advisory bodies on matters of medicines licensing, the MCA is in regular contact with other interested parties, including professional bodies, the NHS and other regulatory organisations. Developments at a European level are having an increasing influence on the legislative framework for medicines. The European Commission has undertaken a major review of Community pharmaceutical law and will be proposing improvements to the licensing system during the latter part of 2001. The MCA will take a leading role in EU discussions on the future of the medicines licensing system.

6.10 The MDA and the MCA also undertake post-marketing surveillance and manage an adverse events reporting system. Following the recommendations of the Chief Medical Officer's expert group on learning from adverse events in the NHS to prevent recurrence, the Department has established a new agency the **National Patient Safety Agency** which will run a mandatory reporting system for logging all failures, mistakes, errors and near misses to complement the MDA and MCA systems.

6.11 The **Gene Therapy Advisory Committee** (GTAC) oversees all clinical trials involving gene transfer into human subjects. The Committee considers the ethical aspects of

proposals to conduct such research, whilst taking into account the scientific merits and ratios of risk-to-benefit. In January 2001, the committee published new guidance to proposers of gene therapy studies and reports on both recommended practices for clinical trials employing adenoviral vectors and *in utero* gene therapy.

6.12 Although gene therapy promises to be a powerful medical treatment of the future, it remains experimental and as such, could have unforeseen consequences on human health. GTAC has initiated a project to monitor any long-term effects of gene therapy. This is the first study of its kind in the world. The NHS records of patients and any of their offspring will be flagged, while maintaining personal anonymity. Records will subsequently be assessed for any coincidence of ill health amongst trial participants

6.13 In the UK, infertility treatment or research which uses embryos is strictly regulated by the Human Fertilisation and Embryology Act 1990. The Act set up the **Human Fertilisation and Embryology Authority** (HFEA) to monitor and regulate by licensing such treatment and research. The Authority is a Non Departmental Public Body responsible to Parliament through the Secretary of State for Health. It comprises 21 members, including the Chair, and 33 staff.

6.14 Research using embryos may be licensed by the Authority under the 1990 Act provided certain conditions are met. These include that the research is for one of the purposes set out in the Act; or in the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 which extended the purposes to include research into treatments for serious diseases.

6.15 The range of products derived from human tissue has also developed to the point where a proposal for a European directive to regulate them is expected during 2001.

Research governance

6.16 Research is essential to the successful promotion and protection of health and well-being and to modern and effective health and social care services. At the same time research can involve an element of risk, both in terms of return on investment and sometimes for the safety and well-being of the research participants. Proper governance of research is therefore essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.

6.17 The Department, through consultation, has developed a **Research Governance Framework** for health and social care, which was issued in March 2001. The Framework sets out the legal requirements and standards expected, and the relative roles and responsibilities, of all those involved in research funder, host, sponsor, researcher and participants. Ensuring implementation of the framework will be a major priority over the next two years.

6.18 In response to public concern, the Department is also leading work with the involvement of patients and professionals to develop requirements on **consent for treatment and research**, and producing new guidance and introducing changes in legislation covering retention of organs and tissue following the Alder Hey Inquiry.

6.19 The Department also has responsibility for **Research Ethics Committees** (RECs) whose approval is required for any research being undertaken in the NHS involving patients. As well as introducing Multicentre Research Ethics Committees to manage proposals for research to be undertaken in more than one NHS Trust, the Department has also set up the Central Office for Research Ethics Committees (COREC) to provide support and training for RECs and to help streamline processes. New governance arrangements for NHS Research Ethics Committees were put out for

Patient confidentiality

6.20 The existing legal framework around the control of **confidential information relating to patients** is complex and contains uncertainties. There are no powers in the legislation to simplify or clarify the framework or to regulate the use of information concerning patients. Recent guidance from the General Medical Council has brought this issue to the fore with doctors being unclear about when it is or is not lawful for them to share confidential information with others. This has particular implications for medical research, including epidemiological studies. The **Health and Social Care Act 2001** makes provision (at Section 60) for the making of regulations both restricting and allowing disclosure of information.

6.21 The Department has lead responsibility for the **Human Genetics Commission** (HGC) which advises Health and Science Ministers on how new developments in human genetics will impact on people and on health care. HGC has a particular focus on the social, ethical, legal and economic implications of developments and the need to inform and involve the public and other groups as openly as possible. It also has a role in advising on strategic priorities for research and for the delivery of genetic services by the NHS.

6.22 HGCs first major project is an examination of how personal genetic information is treated in medical research, medical practice and for non-medical applications and what may need to be done to ensure that concerns over the potential abuse of such information are addressed. A consultation on these issues (Whose hands on your genes?) was recently concluded and a report of a MORI survey (Public attitudes to human genetic information) recently published. HGC will report to Ministers with its recommendations by autumn 2001. Some of the specific issues that HGC is considering in the field of medical research are: the consent of research participants (including in future large-scale genetic databases linked to health records and in historical collections); feedback to research participants; confidentiality and commercial use of genetic information.

Involving consumers in research and the Scientific Advisory system

6.23 The Department has recognised the need to involve a broad range of stakeholders in the research agenda, and an important part of this is the involvement of **consumers**. The Department has a Standing Group on Consumers in NHS Research which aims to ensure that consumer involvement in research improves the way that research is prioritised, commissioned, undertaken, disseminated and used. Members come from consumer organisations, research, health information, health service management and social services. A number of reports and guidance on involving consumers have been issued by the Group.

6.24 The important principle that every major committee or advisory body in the NHS R&D programmes should normally have two consumer representatives has been established, for example the Health Technology Assessment Programme has consumers on all its Advisory Panels. Consumer and patient groups are also included in consultation about priorities for specific research programmes.

6.25 A mobile phone research workshop held in February 2001 had a variety of stakeholders - including consumers, special interest groups and industry - discussing the research programme being set up.

6.26 The Department is also involving lay members on Scientific Advisory Committees. Several of these Advisory Committees, even those with a remit to advise on purely technical matters, have lay or consumer members. For example, both the Committee on Carcinogenicity (COC) and the Committee on Mutagenicity (COM) have lay members. Lay members play a crucial role in scrutinising the risk management process and ensuring that advice is presented in a way the public can understand.

Chapter 7

Departmental resources to deliver science and innovation

Responsibilities for science and innovation

Scientific capacity and capability in the Department of Health

Scientific capacity in the NHS

Research funds

Responsibilities for science and innovation in the Department of Health

7.1 The Department's Director of Research and Development currently has responsibility for research, innovation, analytical services and information. The Chief Medical Officer has responsibility for the Scientific Advisory Committees run by the Department of Health.

Scientific capacity and capability in the Department of Health

7.2 Within the Department of Health relevant core expertise is provided by scientists and medical doctors, as well as other professional staff, working in multi disciplinary teams across the Department. This integrated style of working means that there is no "Medical" division comprising doctors and no "Science" division consisting of scientists, most of whom are in the Public Health Group.

7.3 There are currently around 43 scientists in Department of Health's headquarters but there are many more in its agencies and Non-Departmental Public Bodies such as the Public Health Laboratory Service and the National Radiological Protection Board. The Department is currently assessing its need for scientific staff in the light of the Phillips Inquiry Report. The Department's recruitment strategy ensures that it continues to get high quality scientists; the strategy includes open competitions to fill specialist posts, and involvement of the Head of Profession for Scientists in the recruitment process who also ensures that those recruited have the necessary communication skills to explain complex science to non-scientists. The Department of Health supports its scientists as a group through the Head of Profession and by offering opportunities for career advancement through secondment to outside organisations such as the OECD.

7.4 The Department does not generally encounter problems in attracting high quality candidates; usually there are large fields of applicants for scientific posts. However, there may be difficulties in retention; moves to contract out scientific work and move scientists to agencies leaves scientists in the Department of Health more isolated with less of a critical mass of scientific posts to allow career development. If the outcome of the post Phillips Inquiry assessment is that the Department of Health needs more scientists, then the difficulty in times of competing resources is likely to be identifying and releasing the necessary funding.

7.5 The Department of Health has approximately 150 medical doctors, about a third of whom work in the Medicines Control Agency. Since 1996 the Department has employed doctors at consultant level only. As a result, at least 36 of the 150 have consultant status and have met the requirements of the NHS Appointments Advisory Committee prior to appointment.

7.6 The Department has a Research and Development Directorate which includes professional staff with backgrounds in a range of research areas; they manage the Policy Research Programme portfolio. Senior managers in the Directorate also have research backgrounds. NHS Regional Offices also have Regional Directors of R&D with professional research backgrounds who are professionally accountable to the Department's Director of R&D. Most programme management for the national NHS R&D Programmes is sub-contracted. The Programme Directors all have professional research backgrounds.

7.7 Other professional staff in the Department includes statisticians, economists, operational researchers and epidemiologists. The Department has a social science based analytical strategy, which has links to some aspects of the Science and Innovation Strategy. The Department is aware of the need to ensure that these strategies support each other. For example, innovative knowledge management might improve the science strategy, and technological innovation could be focused by better analyses. The Department's Director of R&D has recently taken over responsibility for analytical services in the Department and is reviewing how these services can be better integrated.

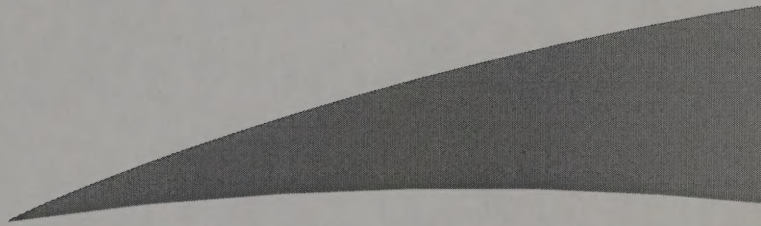
Scientific capacity in the NHS

7.8 There are more than 20 professional groups of healthcare scientists in the NHS. The Department's aim is to develop a scientific and technical workforce of sufficient size and with the necessary competencies to deliver high quality science based healthcare services. Delivery will be achieved through interactions with education providers in the higher and further education sectors and by the provision of skills based training on-site to nationally agreed standards.

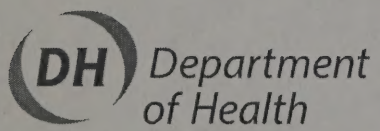
7.9 The development of improved education and training frameworks will facilitate the creation of competent multi-disciplinary teams of health professionals able to fulfil the objectives of the NHS Plan. The key issues to address are ensuring that those leaving further/higher education have access to a Science and Technology knowledge base that is fit-for-purpose for entry into their particular speciality, and development of a comprehensive occupational standards framework.

Research funds

7.10 The Department currently devotes over £500 million per annum to research expenditure. Of this currently £476m is allocated to NHS Research and Development and comes directly from the Health and Community Health Services budget. The Policy Research Programme, about £28m per annum, other Public Health R&D budgets and Research and Development budgets for Non-Departmental Public Bodies (about £30 million in total) are funded from the Department's administrative budget. The NHS Research and Development and Policy Research Programme budgets are held and managed by the Department's Director of Research and Development. Research and Development budgets are set annually through discussion with Ministers.



This document is available at www.doh.gov.uk/research.



First Published: September 2001

